

WHAT IS CLAIMED IS:

- 1                   1.       A balloon catheter having a spirally folded balloon comprising:  
2                   a catheter body having a proximal end and a distal end; and  
3                   a radially expansible balloon near the distal end of the catheter body, the  
4 balloon comprising a proximal end, a distal end, and at least one permanent fold line formed  
5 on the balloon prior to folding, the fold line extending helically along at least a portion of the  
6 surface of the balloon.
- 1                   2.       A balloon catheter as in claim 1, wherein the radially expansible  
2 balloon comprises two to five helical fold lines extending helically along at least a portion of  
3 the surface of the balloon.
- 1                   3.       A balloon catheter as in any one of claims 1 or 2, wherein each fold  
2 line is parallel to each other.
- 1                   4.       A balloon catheter as in claim 3, wherein the fold lines are equally  
2 spaced apart.
- 1                   5.       A balloon catheter as in any one of claims 1 or 2, wherein the at least  
2 one fold line comprises a groove in the balloon.
- 1                   6.       A balloon catheter as in any one of claims 1 or 2, wherein the at least  
2 one fold line comprises a crease in the balloon.
- 1                   7.       A balloon catheter as in any one of claims 1 or 2, wherein the balloon  
2 is folded along the preformed fold lines to form lobes.
- 1                   8.       A balloon catheter as in any one of claims 1 or 2, wherein the balloon  
2 is folded along the preformed fold lines to form flaps.
- 1                   9.       A balloon catheter as in claim 1 or 2, further comprising a scoring  
2 structure adjacent to the fold lines.
- 1                   10.      A balloon catheter as in claim 9, wherein the scoring structure  
2 comprises at least one scoring element spirally circumscribing the balloon.

- 1                    11.     A balloon catheter as in claim 10, wherein the scoring element  
2 continuously circumscribes the balloon.
- 1                    12.     A balloon catheter as in claim 10, wherein the scoring element  
2 comprises a plurality of segments.
- 1                    13.     A balloon catheter as in claim 10, wherein the scoring element  
2 comprises a wire.
- 1                    14.     A balloon catheter as in claim 10, wherein the scoring element is  
2 secured to an outer surface of the balloon.
- 1                    15.     A balloon catheter comprising:  
2                    a catheter body having a proximal end and a distal end; and  
3                    a radially expansible balloon near the distal end of the catheter body, the  
4 balloon comprising a proximal end, a distal end, and at least one recess extending helically  
5 along at least a portion of the surface of the balloon; and  
6                    at least one helical scoring structure located within the helical recess of the  
7 balloon, wherein the helical recess shields the scoring structure from exposure when the  
8 balloon is not expanded.
- 1                    16.     A balloon catheter as in claim 15, wherein the scoring structure  
2 comprises at least one scoring element spirally circumscribing the balloon.
- 1                    17.     A balloon catheter as in claim 16, wherein the scoring element  
2 continuously circumscribes the balloon.
- 1                    18.     A balloon catheter as in claim 16, wherein the scoring element  
2 comprises a plurality of segments.
- 1                    19.     A balloon catheter as in claim 16, wherein the scoring element  
2 comprises a wire.
- 1                    20.     A balloon catheter as in claim 16, wherein the scoring element is  
2 secured to an outer surface of the balloon.

- 1                   21.     A method of folding a balloon on a balloon catheter for insertion in a  
2 body lumen, the method comprising:  
3                   providing a balloon having at least one fold line formed in a wall of the  
4 balloon and extending helically along the outer surface of the balloon; and  
5                   folding the balloon along the at least one helical fold line.
- 1                   22.     A method as in claim 21, wherein the at least one fold line is created  
2 by scoring the balloon.
- 1                   23.     A method as in claim 22, wherein scoring the balloon comprises:  
2 advancing the balloon relative to a fixture having at least one scoring element;  
3 and  
4                   scoring the balloon to create a score that extends helically along an outer  
5 surface of the balloon.
- 1                   24.     A method as in claim 23, wherein the balloon is advanced relative to a  
2 stationary fixture.
- 1                   25.     A method as in claim 23, wherein the fixture is advanced relative to a  
2 stationary balloon.
- 1                   26.     A method as in claim 23, wherein the fixture has between two and  
2 five scoring elements.
- 1                   27.     A method as in claim 26, wherein the scoring elements comprise  
2 lasers.
- 1                   28.     A method as in claim 26, wherein the scoring elements comprise  
2 scoring blades.
- 1                   29.     A method as in claim 28, wherein the fixture further comprises an  
2 opening, the scoring blades positioned to converge on the opening, wherein the balloon is  
3 axially advanced through the opening to score the balloon.
- 1                   30.     A method as in claim 29, wherein the scoring blades individually rotate  
2 about a mounting axis of each scoring blade as the balloon is advanced through the opening.

1                    31.     A method as in claim 30, wherein the balloon is rotated as it is  
2     advanced through the opening.

1                    32.     A method as in claim 28, further comprising heating the scoring  
2     blades.

1                    33.     A method as in claim 30, wherein the scoring blades are canted so as to  
2     force the balloon to rotate as it is advanced through the opening of the fixture.

1                    34.     A method as in claim 31, wherein folding the balloon along the helical  
2     fold line comprises inserting the balloon into a press.

1                    35.     A method as in claim 34, further comprising heating the press.

1                    36.     A method as in claim 23, wherein the balloon is inflated to a  
2     predetermined pressure prior to advancing the balloon relative to a fixture, and wherein the  
3     balloon is deflated at a predetermined rate as it is being scored.

1                    37.     A method as in claim 36, wherein the balloon is inflated to a range  
2     between 15 psi and 400 psi.

1                    38.     A method as in claim 37, wherein the balloon is deflated at a rate in the  
2     range between 1 psi/sec and 150 psi/sec.

1                    39.     A method as in claim 21, wherein the at least one fold line is created  
2     by permanently creasing the balloon.

1                    40.     A method as in claim 39, wherein permanently creasing the balloon  
2     comprises:  
3                    advancing a portion of the balloon into a press comprising a plurality of  
4     helical folding plates, the helical plates positioned adjacent to each other to form one or more  
5     helical gaps, wherein the portion of the balloon is positioned in the one or more helical gaps  
6     between the helical plates; and  
7                    pressing the plates together to form at least one fold line extending helically  
8     along an outside surface of the balloon.

1                   41.     A method as in claim 40, wherein the press comprises two to five  
2     helical folding plates to create a plurality of fold lines extending helically along an outside  
3     surface of the balloon.

1                   42.     A method as in claim 41 further comprising an expandable support,  
2     wherein the folding plates are held adjacent to each other by the expandable support.

1                   43.     A method as in claim 42, wherein prior to advancing the balloon into  
2     the press, the expandable support is sufficiently expanded to allow the balloon to be  
3     positioned between the mating surfaces of the helical folding plates.

1                   44.     A method as in claim 42, wherein pressing the plates together  
2     comprises compressing the expandable support.

1                   45.     A method as in claim 42, wherein the balloon is inflated to a  
2     predetermined pressure prior to advancing the balloon relative to a fixture, and wherein the  
3     balloon is deflated at a predetermined rate as it is being scored.

1                   46.     A method as in claim 45, wherein the balloon is inflated to a range  
2     between 15 psi and 400 psi.

1                   47.     A method as in claim 45, wherein the balloon is deflated at a rate in the  
2     range between 1 psi/sec and 150 psi/sec.

1                   48.     A method as in claim 21, wherein the at least one helical fold line is  
2     created by heating a portion of the balloon in a helical pattern.

1                   49.     A method as in claim 48, wherein heating the balloon comprises:  
2                   providing an expansible cage having at least one helical segment, wherein the  
3     number of helical segments corresponds to the number of helical fold lines to be fabricated;  
4                   inflating the balloon inside the cage so that the balloon contacts the at least  
5     one helical segment;  
6                   heating the cage; and  
7                   radially compressing the cage while deflating the balloon to create at least one  
8     helical fold line along the at least one helical segment.

1                    50.     A method as in claim 49, wherein the cage has two to five helical  
2 segments to create the helical fold lines.

1                    51.     A method as in claim 50, wherein the helical segments comprise wire.

1                    52.     A method as in claim 50, further comprising inserting the compressed  
2 cage and balloon into a tube having an inner diameter such that the balloon is folded over  
3 onto the helical fold line when placed in the tube.

1                    53.     A method as in claim 50, further comprising rolling the balloon so that  
2 the balloon folds helically along the fold line.

1                    54.     A method of treating a body lumen of a patient, the method  
2 comprising:  
3                    providing a catheter having a balloon with at least one fold line formed in the  
4 wall of the balloon and extending helically along the outer surface of the balloon,  
5                    inserting the catheter in its helically-folded state into the body lumen;  
6                    advancing the catheter to a treatment site within the lumen; and  
7                    inflating the balloon to engage a wall of the lumen to treat the lumen.

1                    55.     A method as in claim 54, further comprising:  
2                    deflating the balloon so that the at least one fold collapses into the helically  
3 compressed state to disengage the wall of the lumen; and  
4                    removing the catheter from the lumen

1                    56.     A device for fabricating a radially expansible balloon for a balloon  
2 catheter, the balloon having at least one helical fold, the device comprising:  
3                    a base,  
4                    a mounting fixture connected to the base, the mounting fixture adapted to  
5 receive the balloon;  
6                    means for advancing the balloon relative to the mounting fixture; and  
7                    at least one scoring element mounted to the mounting fixture, wherein the  
8 number of scoring elements corresponds to the number of helical folds to be fabricated; and  
9 wherein the at least one scoring element converges on the balloon as it is advanced so that the

10 scoring element creates at least one score extending helically along the outer surface of the  
11 balloon, the helical score allowing the balloon to be helically folded along the score.

1 57. A device as in claim 56, wherein the fixture has between two and five  
2 scoring elements.

1 58. A device as in claim 57, wherein the scoring elements comprise lasers.

1 59. A device as in claim 57, wherein the scoring elements comprise  
2 scoring blades.

1 60. A device as in claim 59, wherein the fixture further comprises an  
2 opening, the scoring blades positioned to converge on the opening, wherein the balloon is  
3 advanced through the opening to score the balloon.

1 61. A device as in claim 60, wherein the scoring blades comprise discs  
2 rotatably mounted on the fixture, and wherein the discs roll along the outside surface of the  
3 balloon as it is advanced past the opening.

1 62. A device as in claim 61, wherein fixture is rotatably mounted to the  
2 base, and wherein the base further comprises a means for rotating the fixture at a  
3 predetermined rate.

1 63. A method as in claim 61, wherein the scoring blades are canted so as to  
2 force the balloon to rotate as it is advanced through the opening of the fixture.

1 64. A device as in claim 61, further comprising means for heating the  
2 scoring blades.

1 65. A device for fabricating a radially expansible balloon for a balloon  
2 catheter, the balloon having at least one helical fold, the device comprising:  
3 a plurality of helical plates placed adjacent to each other to form at least one  
4 helical gap;  
5 a support for the holding the helical plates together, the collar being adjustable  
6 to permit the size of the at least one helical gap to be modified; and  
7 means for applying pressure to press the helical plates together, wherein a  
8 portion of the balloon may be inserted between the helical plates and pressed to form at least

9 one fold line extending helically along an outer surface of the balloon, and wherein the  
10 balloon may be spirally folded along the fold line.

1 66. A device as in claim 65, further comprising means for heating the  
2 plates.

1 67. A device as in claim 65, wherein adjusting the collar provides means  
2 for applying pressure to the press.

1 68. A device for fabricating a radially expansible balloon for a balloon  
2 catheter, the balloon having at least one helical fold, the device comprising:  
3 an expansible cage having at least one helical segment, wherein the number of  
4 helical segments corresponds to the number of helical fold lines to be fabricated; and  
5 a heat source coupled to the cage;  
6 wherein the heat source heats the cage to create the at least one helical fold  
7 line.

1 69. A device as in claim 68, wherein the cage has two to five helical  
2 segments to create the helical fold lines.

1 70. A device as in claim 69, wherein the helical segments comprise wire.

1 71. A device as in claim 69, wherein the caged is configured to fit around  
2 the circumference of the balloon so that the helical segments contact the balloon when the  
3 balloon is in an inflated configuration, and wherein the cage collapses with the balloon when  
4 the balloon is deflated.

1 72. A device as in claim 71, wherein the cage further comprises a scoring  
2 structure that is delivered with the balloon catheter for treatment of a body lumen.

1 73. A device as in claim 68, further comprising an over tube, the over tube  
2 having an inner diameter such that the balloon is folded over onto the at least one helical fold  
3 line when placed in the tube.